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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,142	07/24/2003	Paul A. Burgio	58359US003	9324
32692	7590	01/25/2006	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			GRAFFEO, MICHEL	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/626,142	Applicant(s) BURGIO ET AL.	
	Examiner Michel Graffeo	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

Claims 1-80 are pending and examined.

Applicant has provided arguments for the patentability of claims 1-80 in the response filed 18 November 2005. Applicant's arguments with respect to claims 1-80 have been considered but are moot in view of the new ground(s) of rejection. Any rejection not specifically stated in this Office Action has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-12, 14-20, 22-27, 29, 46-49 and 57-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose or an applicant may show possession of an invention by disclosure of drawings or structural

chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. A "fluoride releasing group" is described in the specification on page 11 as the following:

20 ***FLUORIDE RELEASING GROUPS***

Suitable fluoride releasing groups include fluoride salts as disclosed, for example, in U.S. Pat. Nos. 5,607,663 (Rozzi et al.), 5,662,887 (Rozzi et al.), 5,866,630 (Mitra et al.), 5,876,208 (Mitra et al.), 5,888,491 (Mitra et al.), and 6,312,668 (Mitra et al.). A preferred fluoride releasing group includes
25 tetrafluoroborate anions as disclosed, for example, in U.S. Pat. No. 4,871,786 (Aasen et al.). A preferred repeating unit of a fluoride releasing group includes trimethylammoniummethyl methacrylate.

Besides the tetrafluoroborate listed and the fluoride releasing groups disclosed in EP 0363095 to Minnesota Manufacturing and Mining Company, no other definition or explanation by way of example or function are provided for a "fluoride releasing group". Moreover, the instant Specification points to US Patent No. 5,607,663 and US Patent No. 6,312,668 for suitable fluoride releasing groups both of which contain virtually the same language cited as art over the instant claims and argued by Applicant. Therefore, the recitation of "fluoride releasing group" is not enabled by the Specification to one of ordinary skill in the art.

Claims 1-6, 8-12, 14-20, 22-27, 29, 46-49 and 57-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a dental whitening composition comprising trimethylammoniummethyl methacrylate

Art Unit: 1614

tetrafluoroborate as a fluoride releasing group that performs unexpectedly better than the prior art, does not reasonably provide enablement for all fluoride releasing agents outside of those disclosed in EP 0363095 to Minnesota Manufacturing and Mining Company. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and ,
- 8) the relative skill of those skilled in the art.

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

- 1) the nature of the invention; the invention is directed to a dental whitening composition.
- 2) the breadth of the claims; the scope of the claims includes all fluoride releasing groups.

- 3) the predictability or unpredictability of the art; as noted above, without a clear description of “fluoride releasing group”, one of ordinary skill in the art would not be able to predict the functional efficacy of such a group. Other than the groups disclosed in EP 0363095 to Minnesota Manufacturing and Mining Company, the instant Specification does not provide any written description of a “fluoride releasing group” other than a list of references, most if not all of which are cited as equivalent to the below cited Mitra et al. reference (see rejection under 35 USC §103).
- 4) the amount of direction or guidance presented; the specification does not provide any guidance for the use of a “fluoride releasing group” other than the showing that trimethylammoniummethyl methacrylate tetrafluoroborate works better than another fluoride releasing group; dimethylhexadecylammoniummethyl methacrylate bromide.
- 5) the presence or absence of working examples; other than the working examples noted above, there is no description for nor working examples of additional “fluoride releasing groups”. Note that in cases involving physiological activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).
- 6) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as

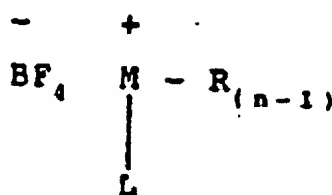
"sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of the functionality of "fluoride releasing groups", and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 102

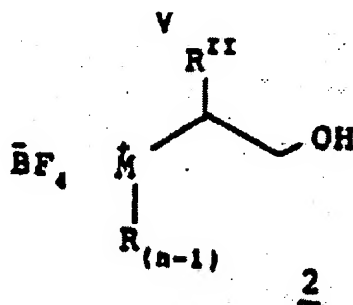
Claims 1-3, 23-25, 30-32, 46, 49-50, 53-56 and 65-72 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0363095 to Minnesota Manufacturing and Mining Company.

The EP 0363095 reference discloses sealants, adhesives and the like (in current claims see page 3 lines 12-15) that are for example, brushed onto a dental surface (in current claims 53-56 and 65-72; see page 8 line 15) comprising tetrafluoroborate ions as fluoride releasing groups wherein the fluoride sources are compounds of Formula II:



II

wherein n is 4, R is methyl and further wherein the compounds of Formula II may serve as polymerizable fluoride sources if the R value comprises a moiety such as a methacrylate (see page 5 lines 40-45) as well as the compounds having the following formula comprising a hydrophobic fluorine-containing group:

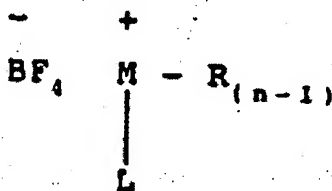


The EP 0363095 reference also teaches fluoride releasing groups such as tetramethylammonium tetrafluoroborate, which absent evidence to the contrary, have the same functionality as trimethylammoniummethyl tetrafluoroborate as well as a fluoride source that may be polymerizable with a polymerizable monomer comprising straight or branched alkyl chains (in current claims 1-3, 23-25, 30-32, 46, 49-50; see page 3 lines 24-40). Finally, the EP 0363095 reference teaches peroxides which after application to the tooth are exposed to light (see page 7 lines 55-end).

Claim Rejections - 35 USC § 103

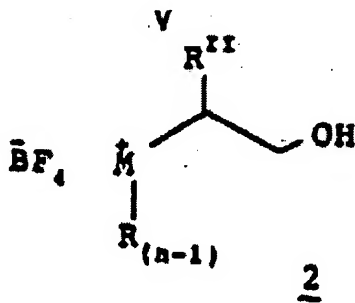
Claims 1-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0363095 to Minnesota Manufacturing and Mining Company and further in view of US Patent No. 6,083,421 to Huang et al.

The EP 0363095 reference discloses sealants, adhesives and the like (in current claims see page 3 lines 12-15) that are for example, brushed onto a dental surface (in current claims 53-56 and 65-72; see page 8 line 15) comprising tetrafluoroborate ions as fluoride releasing groups wherein the fluoride sources are compounds of Formula II:



II

wherein n is 4, R is methyl and further wherein the compounds of Formula II may serve as polymerizable fluoride sources if the R value comprises a moiety such as a methacrylate (see page 5 lines 40-45) as well as the compounds having the following formula comprising a hydrophobic fluorine-containing group:



The EP 0363095 reference also teaches fluoride releasing groups such as tetramethylammonium tetrafluoroborate, which absent evidence to the contrary, have the same functionality as trimethylammoniummethyl tetrafluoroborate as well as a fluoride source that may be polymerizable with a polymerizable monomer comprising straight or branched alkyl chains (1-3, 23-25, 30-32, 46, 49-50; see page 3 lines 24-40). Finally, the EP 0363095 reference teaches peroxides which after application to the tooth are exposed to light (see page 7 lines 55-end).

The EP 0363095 reference does not teach any particular amounts of peroxides.

Huang et al. further teach that oxides such as carbamide peroxide can be present in an amount of from 6 to about 20% (in current claims 4, 8-14, 18, 26, 33, 37-40, 44, 46-51, see Abstract).

One skilled in the art would be motivated to combine the EP 0363095 reference with Huang et al. since both are directed to teeth whitening compositions comprising peroxides which can be applied as a topical coating (see col 2 lines 35-40). Thus, the claimed invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0363095 to Minnesota Manufacturing and Mining Company as applied to claims 1-80 above taken with US Patent No. 4,018,732 to Lakshmanan.

The EP 0363095 reference does not recite the hydrophobic hydrocarbon octadecylacrylate specifically.

Lakshamanan discloses an oral adhesive material with includes octadecyl acrylate (see col 1 lines 54-55).

One of skill in the art would be motivated to combine the EP 0363095 reference with Lakshamanan and as combined would make the above claim obvious. Both references are directed to oral care compositions. Further, the EP 0363095 reference describes a hydrophobic composition such that one skilled in the art would expect success by substituting the octadecyl acrylate of Lakshamanan for the acrylate page 5 line 43 of the EP 0363095 reference. Thus, the claimed invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Response to Arguments - 35 USC § 102

Applicant's arguments, see Response, filed 18 November 2005, with respect to the rejection(s) of claim(s) 1-5, 8-11, 14-19, 22, 30-34, 36-48 and 50-80 under 35 USC § 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of EP 0363095 to Minnesota Manufacturing and Mining Company. The comments in the response do not address this reference with regard to the currently presented anticipation rejection.

Response to Arguments - 35 USC § 103

Applicant's arguments, see Response, filed 18 November 2005, with respect to the rejection(s) of claim(s) 1-80 under 35 USC § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of EP 0363095 to Minnesota Manufacturing and Mining Company and further in view of US Patent No. 6,083,421 to Huang et al. The comments in the response do not address this reference with regard to the currently presented obviousness rejection. Specifically, the comments on page 11 of the response file 18 November 2005 have been considered but are unpersuasive. Applicant states that the EP 0363095 reference does not teach a whitening agent as claimed in the instant application. As discussed in the above rejection the EP 0363095 reference does, contrary to Applicant's position, does teach a whitening agent.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 January 2006

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